

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Marco FILICORI  
Title: UNITARY COMBINATION OF  
FSH AND hCG  
Appl. No.: Unassigned  
Filing Date: Herewith  
Examiner: Herewith  
Art Unit: Herewith

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

**RELEVANCE OF EACH DOCUMENT**

The listed documents were cited as being relevant during the prosecution of the corresponding International application. Copies of the documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date December 2, 2005

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10/559610

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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APPROPRIATE PTO 02 DEC 2005

Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: December 2, 2005  (use as many sheets as necessary)				Application Number	Unassigned
				Filing Date	Herewith
				First Named Inventor	Marco Filicori
				Group Art Unit	Unassigned 1647
				Examiner Name	Unassigned RM DeBerry
Sheet	1	of	1	Attorney Docket Number	052209-0143

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
RMD	A1	EP	1 364 658	A	APPLIED RESEARCH SYSTEMS	11/26/2003		
	A2	WO	00/67778	A	APPLIED RESEARCH SYSTEMS	11/16/2000		
	A3	WO	03/022302	A	APPLIED RESEARCH SYSTEMS	03/20/2003		
RMD	A4	WO	03/022303	A	APPLIED RESEARCH SYSTEMS	03/20/2003		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
RMD	A5	FILICORI ET AL., "Stimulation and Growth of antral ovarian follicles by selective LH activity administration in women," <i>Journal of Clinical Endocrinology and Metabolism</i> , March 2002, pp. 1156-1161		
	A6	FILICORI ET AL., "Luteinizing hormone activity supplementation enhances follicle-stimulating hormone efficacy and improves ovulation induction outcome," <i>Journal of Clinical Endocrinology and Metabolism</i> , vol. 84, no. 8, August 1999, pp. 2659-2663.		
RMD	A7	THOMPSON ET AL., "Gonadotrophin requirements of the developing follicle," <i>Fertility and Sterility</i> , vol. 63, no. 2, February 1995, pp. 273-276.		

Examiner Signature	ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH	Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.